VIA ECF

May 28, 2020

The Honorable Theodore D. Chuang
United States District Court
District of Maryland
6500 Cherrywood Lane, Suite 245A
Greenbelt, MD 20770

Re: *American College of Obstetricians and Gynecologists et al. v. U.S. Food and Drug Administration et al.*, Civil Action No. TDC-20-1320: Notice of Intent to File Motion

Dear Judge Chuang:

We write pursuant to § II.A of the May 28, 2020, Case Management Order (Dkt. 22) in the referenced case, concerning Plaintiffs' motion for a preliminary injunction against Defendants U.S. Food and Drug Administration ("FDA") et al. Plaintiffs' motion (previously filed at Dkt. 11 & 12)[1] seeks to enjoin enforcement of certain requirements of the Risk Evaluation and Mitigation Strategy ("REMS") program for mifepristone, an FDA-approved prescription medication used for early abortion and miscarriage care, that are unnecessarily exposing patients, clinicians, and their families to life-threatening risks during the COVID-19 pandemic.

The primary challenged aspect of the mifepristone REMS requires that, after a clinician has determined (either through telehealth or at a prior in-person visit) that mifepristone is appropriate for their patient, the patient must make an unnecessary trip to a hospital, clinic, or medical office to pick up the pill (the "Mifepristone In-Person Dispensing Requirement" or "the Requirement"). This mandate applies even when the patient will be receiving no in-person medical services, and will swallow the pill later at home, which the FDA permits.

Recognizing the risks associated with travel and in-person encounters during this crisis, Defendants acted rapidly in March to suspend other federal requirements necessitating in-person health care visits and afford clinicians greater discretion to avoid needless viral exposure risks for themselves, their staff, and their patients. *See* Compl. ¶¶ 83-90. Starting on March 27, 2020, numerous medical and public health authorities, including several of the plaintiffs here, formally requested the FDA to similarly suspend the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic because it provides no benefit while imposing severe medical risks on patients and clinicians. *See* Compl. Exs. 3-6. Defendants have maintained the Requirement despite these requests, and failed to offer any explanation for their constructive denial or for continuing to expose Plaintiffs, Plaintiffs' members, and their patients to unnecessary risk.

[1] Plaintiffs filed the motion prior to the issuance of the Case Management Order and are prepared to re-file if directed by the Court.

Grounds for Filing Motion for Preliminary Injunctive Relief

Plaintiffs include the American College of Obstetricians and Gynecologists, the nation's premier professional membership organization for obstetrician-gynecologists, with more than 60,000 members, and the Council of University Chairs of Obstetrics and Gynecology, representing the departments chairs of obstetrics and gynecology at nearly 150 universities. Plaintiffs respectfully seek a preliminary injunction on the following grounds:

First, Plaintiffs are likely to succeed in proving that Defendants' retention of the Mifepristone In-Person Dispensing Requirement during the COVID-19 pandemic violates the United States Constitution. The Requirement forces patients to needlessly expose themselves to heightened risk of contracting a life-threatening disease as a condition of obtaining abortion care in violation of the due process clause of the Fifth Amendment. In addition, in violation of the Fifth Amendment's equal protection clause, it subjects Plaintiffs, Plaintiffs' members, and their patients seeking abortion or miscarriage care to heightened risk of exposure while affording similarly situated clinicians and patients the ability to avoid such needless risk during the pandemic, without sufficient—indeed, any—justification.

Second, the Mifepristone In-Person Dispensing Requirement is causing immediate irreparable harm. In addition to causing constitutional injury to Plaintiffs, their members, and the patients they treat—which alone establishes irreparable harm, *see, e.g.*, *Ross v. Messe*, 818 F.2d 1132, 1135 (4th Cir. 1987)—the Requirement is infringing the clinical judgment of Plaintiffs and their members and is subjecting patients, their families, and their clinicians to unnecessary and serious medical risks. The Requirement is causing particular harm to low-income people and people of color, who are most at risk for severe illness and death from COVID-19.

Finally, the balance of equities and the public interest overwhelmingly favor injunctive relief. The Mifepristone In-Person Dispensing Requirement is imposing life-threatening health risks on patients, clinicians, and the broader public with no countervailing benefit. Enjoining enforcement of the Requirement during the pandemic will mitigate viral spread while causing Defendants no harm. Indeed, such relief is entirely consistent with the substantial action Defendants have taken to limit unnecessary travel and in-person health care encounters during the COVID-19 pandemic for other medications and services—actions from which Defendants have discriminatorily carved out mifepristone prescribers and their patients.

Pre-Hearing Efforts to Meet and Confer

Plaintiffs emailed a courtesy copy of the complaint and motion for preliminary injunction to the U.S. Attorney on May 27, and sent follow-up emails on May 28 offering to meet and confer. Counsel for the parties are scheduled to meet and confer at 11:00 am tomorrow, May 29, 2020.

Request for Expedited Hearing

Given the urgent need for relief, Plaintiffs also respectfully request that the Court set a date for argument as soon as the Court's schedule permits.

Respectfully submitted,

/s/ John Freedman

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